APR 0 9 2003

K030940

MICROVISION

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6) 510(k) Summary

Date:

Company Name and Address
Microvision Incorporated
19910 North Creek Parkway
Bothell, WA 98011

Contact Person
Karl Bylund
Regulatory and Compliance Engineer
Telephone: 425-415-6634

Device Trade Name
Nomad™ ND1000M Augmented Vision System

Common Name
Video Monitor

Classification Name
Endoscope and Accessories

Predicate Devices

1) Device name: Head Mounted Display
Manufacturer: Vista Medical Technologies
5451 Avenida Encinas, Suite A
Carlsbad, CA 92008
Classification : Class II
510K Number : K961800
Regulation Number : 876.1500
Product code : GCJ

2) Device name: i-View Personal Video Display
Manufacturer: MediVision Endoscopy Incorporated
1440 S. State College Boulevard, #1D
Anaheim, CA 92806
Classification : Class II
510K Number : K000669
Regulation Number : 876.1500
Product code : GCJ

Nomad™ ND1000M Augmented Vision System 510(k) Submission

Description of the Device

The Nomad™ ND1000M Augmented Vision System is a monochromatic head-worn monocular display. The intended use of the Nomad™ ND1000M system is to display video data or images while worn on the user's head. It can be connected to any SVGA video source. The display combines the ambient environment with the displayed image (the image is superimposed over the normal field of vision). The display may be adjusted over either eye. Optionally, the display may be used in a non see-through fashion (occluded) with addition of the provided ocular cover.

The system consists of a display module, attached to headgear, that is connected via a non-detachable interconnecting cable to a video control electronics module. The video input is connected to the video control electronics module. The device accepts power from a battery or an optional medical grade AC to DC power supply, both supplied with the device. A belt to hold the video control module and battery is provided. A rechargeable Li-Ion battery is also supplied along with a battery charger.

Intended Use

The Nomad™ ND1000M Augmented Vision System is designed to display video data or images while worn on the user's head.

Technological Characteristics Comparison with Predicate Devices

The Nomad™ ND1000M system is similar to the Vista HMD (Head Mounted Display) which received FDA clearance on September 11, 1996 (K961800), and the MediVision i-View Personal Video Display which received FDA clearance on May 26, 2000 (K000669). An exception is that the Nomad™ ND1000M system is monochromatic while the other systems are full color. All of these devices accept video signals and display video data or images while worn on the user's head.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 9 2003

Microvision Incorporated
c/o Mr. Charles Mack
Engineering Team Leader
Underwriters Laboratories, Inc.
2600 NW Lake Road
Camas, Washington 98607-8642

Re: K030940
Trade/Device Name: Nomad™ ND1000M Augmented Vision System
Regulation Number: 21 CFR 876.1500
Regulation Name: Laparoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 21, 2003
Received: March 25, 2003

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030940
Device Name: Video Monitor
Indications For Use:

The intended use of the Nomad™ ND1000M system is to display video data or images while worn on the user's head.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030940